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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,210	02/24/2004	Robert M. Strom	62424A	1668

109 7590 08/15/2005

THE DOW CHEMICAL COMPANY
INTELLECTUAL PROPERTY SECTION
P. O. BOX 1967
MIDLAND, MI 48641-1967

EXAMINER

MAYER, SUZANNE MARIE

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 08/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/785,210	Applicant(s) STROM ET AL	
	Examiner Suzanne M. Mayer, Ph.D.	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,16-19 and 21-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,16-19,21-23,25-27,29-51,53,54,56,57,59,60 and 62-65 is/are rejected.
- 7) ☒ Claim(s) 24,28,52,55,58 and 61 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4-25-2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Status

1. The amendment to the claims and the response to the first Office action filed on April 25, 2005 are acknowledged. Applicant has cancelled claims 3, 7-15 and 20 and has added new claims 23-65; thus claims 1,2,4-6,16-19 and 21-65 are pending and under examination.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on April 25, 2005 has been considered by the examiner. See signed and attached PTO-1449.

Withdrawal of Objections and Rejections

3. In view of the amendments to the application made by Applicant, the objections made to the priority claims, to the oath/declaration and the specification are hereby withdrawn.

The amendments and/or cancellation of claims 1-18 necessitate the withdrawal of claim rejections made under 35 U.S.C. § 102 (b), Seipke et al. and Bazile et al. for claims 1-18.

The amendments to claims 1, 5 and 6 necessitate the withdrawal of claim rejections made under 35 U.S.C. § 112 2nd for claims 1-22.

Maintained Rejections

4. Newly added claims 31-39 and 40-49 are commensurate in scope with previously presented claims 1-2 and 4-6. Newly added claims 23, 25-26, 50-51, 56-57 and 62-63 are commensurate in scope with previously presented claims 21. Newly added claims 27, 29-30, 53-54, 59-60 and 64-65 are commensurate in scope with previously presented claims 22.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-2, 4-6, 19, 21-23, 25-27, 29-51, 53-54, 56-57, 59-60 and 62-65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The details of this rejection is described in the previous Office action.

7. Claim 1-2, 4-6, 19, 21-23, 25-27, 29-51, 53-54, 56-57, 59-60 and 62-65 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that

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the inventors, at the time the application was filed, had possession of the claimed invention. The details of this rejection is described in the previous Office action.

Response to Arguments

8. Applicant's arguments filed April 25, 2005 have been fully considered but they are not persuasive.

Enablement

9. Applicants argue that the amended claims are now fully enabled to one of ordinary skill in the art so that no undue burden of experimentation is present. The examiner respectfully opposes this argument. Specifically, Applicant states on p. 16 3rd paragraph of the Arguments/Remarks: "The specification provides a large number of exemplary periodic antimicrobial peptides, and describes the antimicrobial activities of such peptides based on IC₅₀, MIC and TX₅₀ values, and describes protocols utilized to determine these values." However, it should be noted here that the key word used by Applicant is ***exemplary***. It is clear from this statement that one of ordinary skill in the art may be required to unduly carry out further experimentation in order ascertain if every single peptide which falls within the broad generic formulae of the rejected claims does indeed possess antimicrobial activity. Applicant additionally argues the claims are further enabled because the specification provides methods for selecting and testing the peptides and that in particular, the application discloses for example on p. 5, paragraph 23, Table 1, what the exact peptides are. The examiner does concede this point, that being that Applicant does disclose specific peptides which are antimicrobial in nature and meets all of the limitations of, for example, claim 1. However, this is not what

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Applicant is claiming. Rather, Applicant is claiming 1000's of combinations of potential antimicrobial peptides that may or may not possess antimicrobial activity where the onus falls on the skilled artisan to perform undue and unnecessary experimentation in order to make and or use the claimed invention.

Written Description

10. Applicant argues that the amended claims now meet the requirements for written description and that Tables 1-6 and the additions exemplary antimicrobial peptides in the specification, which are indicative of actual reduction to practice of particular embodiments that meet all of the limitations of the claims. Once again, the examiner concedes that the specific examples outlined in the Tables and in the specification do indeed represent antimicrobial peptides that are species of the broadly claimed generic genus formulae presented in the rejected claims. As previously argued in the previous Office action, that in this case, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the methods of making the claimed invention. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating or making it. The compound itself is required. Thus, it is clear that Applicant was not and is not in possession of every single variation of the generic formulae because as argued by Applicant on p. 18, 1st paragraph, the specification provides a large number of exemplary periodic antimicrobial peptides. The specification, does not, however, provide ALL of antimicrobial peptides found in the formulae as claimed.

New Claim Rejections/Objections

Claim Objections

8. Claim 19 is objected to because of the following informalities: The claim is dependent upon a cancelled claim. Appropriate correction is required.

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. The claimed invention lacks patentable utility. Claims 16-19 are rejected as not having a specific utility because the claims read upon a representative SEQ ID No drawn to specific amino acid sequences: However, only those peptides which are folded properly and possess biological activity possess utility. An unfolded or denatured peptide according to, for example, SEQ ID No: 1, has no utility or antimicrobial activity.

Conclusion

13. Claims 1-2, 4-6, 16-19, 21-23, 25-27, 29-51, 53, 54, 56, 57, 59, 60 and 62-65 are rejected. Claims 24, 28, 52, 55, 58 and 61 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Mayer, Ph.D. whose telephone number

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is 571-272-2924. The examiner can normally be reached on Monday to Friday, 8.30am to 5.00pm.

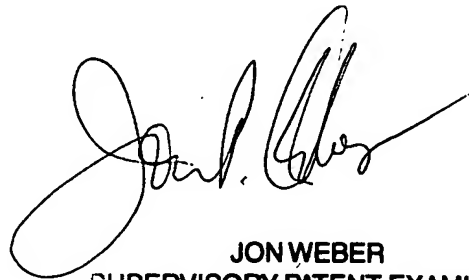
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SMM

09 August 2005



JON WEBER
SUPERVISORY PATENT EXAMINER